REMARKS

In response to the Office Action mailed January 19, 2011, the present application has been carefully reviewed and amended. Entry of the present Amendment and reconsideration of the application are respectfully requested.

Claim Objections

Claims 14 and 30 are objected to because of the recited informalities. These claims have been amended as suggested by the Examiner.

Claim Rejections - 35 USC §112

Claim 31 stands rejected under 35 USC §112 as being indefinite.

Claim 31 has been amended and is believed in compliance with 35 USC §112.

Claim 31 also stands rejected under 35 USC §112 as failing to comply with the written description requirement. Specifically, the Office states "The original disclosure does not support "quantifying a first amount of the indicator passing through the terminal port, and utilizing the quantified first amount in calculating the blood flow rate."" [Paper 20110112, page 3]

The specification provides for the portion of indicator passing through the distal injection port.

[00119] An alternative way of compensation is presented in Figure 12. Here, the catheter 10 is equipped with two thermal dilution sensors 36c, 36d, positioned as shown. The total injected volume of indicator (injectate) V is distributed between the distal injection port with aperture (a×V) and the proximal port(s) with total aperture V(1-a), where "a" is the percentage or portion of the indicator that leaves the catheter through the distal injection port. [1]

The original disclosure further provides for calculating blood flow rate as a function of "a" (the percentage or portion of the indicator that leaves the catheter through the distal injection port). Specifically,

[00123] Subtracting the temperature readings of these two thermal sensors and considering that the inside cooling effect is the same on both sensors, Equations 20 and 21 yield:

$$Q_f = \frac{kV(1-a)(T_b - T_i)}{(S_{sp} - S_{sd})} \qquad \text{Equation 22}$$

Therefore, in view of the original disclosure and the amendments to Claim 31, applicant submits Claim 31 is in compliance with 35 USC §112, first paragraph.

[1] Further description is set forth in [00142] and [00143] in the application as filed.

Double Patenting

Applicant has been advised that if Claim 14 or 30 is found to be patentable, Claim 30 or 14 respectively will be objected to under 37 CFR §1.75 as being a substantial duplicate thereof.

Amended Claim 14 recites in part "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen."

Amended Claim 31 now recites "wherein calculating the blood flow rate includes quantifying a first amount of the indicator passing through the terminal port."

In view of the amendments to Claims 14 and 30, applicant submits the potential issue of double patenting under 37 CFR §1.75 has been obviated.

Rejections under 35 USC §102

Claim 29 stands rejected under 35 USC §102 as being anticipated by US Patent 6,089,103 to Smith ("Smith '103"). [Paper 20110112, page 4]

The prior limitation of "sensing the indicator at a location that is proximal to the terminal port and distal to the injection port" was deemed met by "(...the patient's body, for example the blood cells or blood vessels, would in some way sense the injection of the indicator in the area between the most proximal side port 16 and the terminal port at the end of 14, as the indicator is a volume of cold saline)" [Paper 20110112, page 4]

Applicant respectfully submits the assertion that "the blood cells or blood vessels," would in some way sense the injection of the indicator" does not meet the requirement of "broadest reasonable interpretation consistent with the specification." That is, the specification sets forth in part:

> [0043] As the preferred configuration of the catheter 10 is directed to thermodilution, the dilution sensor 36 is a thermal sensor such as a thermistor. Preferably, the dilution sensor 36 has as small a volume as possible, so that the cross sectional area of the catheter 10 can be effectively minimized. However, it is understood the thermal sensor 36 can be any sensor that can measure temperature, for example, but not limited to thermistor, thermocouple, electrical impedance sensor (electrical impedance of blood changes with temperature change), ultrasound velocity sensor (blood ultrasound velocity changes with temperature), blood density sensor and analogous devices. In fact, any parameter of blood that changes with temperature can be used to obtain thermodilution measurements.
>
> [0044] However, the present invention is particularly applicable to those thermal sensors having a performance that is temperature dependence. That is, those sensors that are effected by induced temperature fluctuations from exposure to a cooled or heated injectate (indicator) passing through the catheter. Temperature sensors are suited to the present invention, as the temperature of the sensor (and hence recorded temperature) can be effected by cooling or heating from the injectate prior to introduction of the injectate into the flow to be measured.

[0045] The dilution sensors 36 detect a blood parameter and particularly variations of a blood parameter. For example, the dilution sensors 36 may be electrical impedance sensors, or optical sensors, the particular sensors being dependent on the blood characteristics of interest. Ultrasound velocity sensors, as well as temperature sensors and optical density, density or electrical impedance sensors can be used to detect changes in blood parameters. The operating parameters of the particular system will substantially dictate the specific design characteristics of the dilution sensor 36, such as the particular sound velocity sensor. If a plurality of dilution sensors 36 is employed, the sensors can be identical components. Ultrasonic sensors measure sound velocity dilution as the indicator material is carried past the sensor by the bloodstream, and changes in sound velocity are plotted to permit calculation of various blood parameters. The time at which the indicator material (injectate) reaches the sensor 36 after injection, the area under the plotted curve representing the changes in sound velocity at the sensor, and the amplitude of the measurement all provide information concerning the blood flow.

There is no disclosure of use of the blood cells or blood vessel cells as the sensor. Applicant respectfully submits the assertion that the previously recited sensing is by the blood cells or the blood vessel cells does not meet the "broadest reasonable interpretation consistent with the specification."

Further, Claim 29 has been amended to recite in part "sensing with a sensor the indicator at a location located along the longitudinal axis intermediate the terminal port and the injection port."

Applicant submits the express recitation of "sensing with a sensor" "at a location located along the longitudinal axis intermediate the terminal port and the injection port" distinctly points out the present subject matter and

overcomes the asserted rejection based on sensing by blood cells and blood vessel cells.

Therefore, the rejection of Claim 29 under 35 USC §102 is believed overcome and this claim is in condition for allowance.

Rejections under 35 USC §103

Claims 14, 17, 19, 20, 28 and 30 stand rejected under 35 USC §103 as being unpatentable over US Patent 6,089,103 to Smith ("Smith '103") in view of US Patent 6,343,514 to Smith ("Smith '514). [Paper 20110112, pages 5-8]

Claims 14 and 30

Smith '103 is relied upon to disclose that less than a total volume of the indicator passed through the indicator lumen is injected in to the blood vessel (see col. 4 lines 19-34). [Paper 20110112, page 6]

This portion of Smith '103 provides that the lumen is filled with indicator - then an amount to be introduced into the vessel is further added to the catheter thereby forcing the same amount from the catheter to the blood vessel.

> When a thermo-dilution measurement is to be performed, the guide catheter **6** is filled entirely all the way up to the distal opening with cold saline, e.g. at a temperature say 10° C. lower than the blood temperature (normally about 37° C.). The temperature is not critical, although it must be enough different from the blood temperature that an adequate gradient be registered. Preferably the temperature of the cold saline is 4–10° C. Then, a small bolus amount, e.g. 0.1 to 5 ml, preferably 0.1 to 2 ml, most preferred 0.1 to 0.5 ml, depending on blood flow, distance between injection and measurement, is injected into the guide catheter **6**, normally at the proximal end. Thereby a corresponding amount will be expelled from the distal opening of the guide catheter and into the blood vessel, and will thereby be transported towards the measurement point by the flowing blood. When the cold saline passes the temperature sensor (col. 4)

That is, all the indicator in Smith '103 that passes through the catheter is injected into the blood stream. The cited portion of Smith '103 cannot mean that less than a total volume of the indicator passed through the indicator lumen is injected in to the blood vessel. Smith '103 provides that once the catheter is full of indicator (without having had any indicator pass from the catheter into the blood vessel), adding a given volume more indicator (i.e., 2ml) to the catheter causes that given volume (2ml) to be forced from the catheter to the blood vessel – while the catheter remains full. Thus, the total volume of indicator that has passed through the Smith '103 catheter is total volume of injected indicator.

Smith '514 is relied upon to disclose "using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44)." [Paper 20110112, page 6]

In contrast, Claims 14 and 30 recite in part "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed

through the indicator lumen" [Claim 14] and "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen and the sensed indicator." [Claim 30].

As neither of the cited references disclose or suggest these limitations, applicant submits the rejection has been overcome.

Claim 17

Claim 17 depends from Claim 14 and includes all the limitations thereof. As neither of the cited references disclose or suggest "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen," Claim 17 is believed in condition for allowance.

Claim 19

Claim 19 depends from Claim 14 and further recites "calculating the blood flow rate comprises compensating for a volume of the indicator passing through the terminal port."

Smith '103 is relied upon to disclose this limitation "by using a total volume."

Applicant submits Smith '103 using the total volume of indicator passing from the catheter does not disclose compensating. Compensating means to offset or adjust. That Smith '103 uses the total volume cannot sustain a rejection of compensating.

Therefore, Claim 19 is believed in condition for allowance.

Claim 20

Claim 20 depends from Claim 14 and further recites "wherein the calculated blood flow rate is described by a relationship $Q = \frac{k(T_b - T_i) \cdot V(1-a)}{S}$."

The rejection under 35 USC §103 is based upon that the blood flow rate "is essentially some numerical value, and any numerical value could be generated using the claimed relationship of claim 20 by selecting the appropriate combination of values for the parameters." [Paper 20110112, page 8]

Claim 20 sets forth a relationship between a blood flow rate and a variety of factors. That the relationship results in a number does not render the relationship inherently obvious.

The Supreme Court in *Diamond v. Diehr*, 450 U.S. 175 (1981) and the US Patent & Trademark Office in issuing US patent 4,344,142, did not consider the use of an equation as obvious. In fact, the following equation is recited in the issued claims of 4,344,142:

$$\ln v = C Z + x$$

In this equation:

ln is the symbol for natural logarithm,

v is the total required cure time and end point for press closure.

C is the activation energy constant, a unique figure for each batch of each compound being molded, determined in accordance with the present invention by rheometer measurements of the batch,

Z is the present mold temperature at 32, and

x is a constant dependent upon the geometry of the particular mold of the press.

Applicant notes this equation also includes a constant x - which by the outstanding rejection could be chosen to provide any numerized value and thus render the claim obvious. However, as in the present claims, the constant in the '142 patent relates to a specific value (a constant dependent upon the geometry of the particular mold of the press) - as the constant in the present claims relates to the thermal capacity of the measured flow and the indicator.

Further, these constants are set forth in terms of a specific item -and are not freely assignable as asserted in the rejection.

In addition, no basis has been indentified in the prior art in of support the rejection of this relationship.

Therefore, Claim 20 is believed in condition for allowance.

Claim 28

Claim 28 depends from Claim 14 and has been amended to recite in part "sensing the indicator along the longitudinal axis intermediate the terminal port and the injection port."

Therefore, applicant submits the rejection based on the sensor 4 of Smith '103 being intermediate the terminal port and the injection port in a direction orthogonal to the longitudinal axis of the catheter 14 has been overcome.

Claim 31

Claim 31 depends from Claim 14 and has been amended to recite in part "wherein calculating the blood flow rate includes quantifying a first amount of the indicator passing through the terminal port." As set forth in Claim 14, the calculating is based upon "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen."

In Smith '103 and Smith '514, V is the volume of injected liquid. In contrast, Claim 31 is in terms of less than the total volume of the indicator. Therefore, applicant submits the rejection of Claim 31 has been overcome.

Claims 16 and 18

Claims 16 and 18 stand rejected under 35 USC 103 in view of Smith '103, Smith '541 and Mahurkar.

Mahurkar does not cure the deficiencies of the combination of Smith '103 and Smith '541. None of the cited references disclose or suggest the limitation of Claim 14 including "calculating the blood flow rate as a function of a volume less than a total volume of the indicator passed through the indicator lumen."

Applicants believe each of pending Claims 14, 16-22, and 28-31 are in condition for allowance. Should the Examiner consider that additional amendments are necessary to place this application in condition for allowance, the favor is requested of a telephone call to the undersigned for the purposes of discussing such amendments.

Please grant any extensions of time necessary for the filing of this Amendment. Please also charge any additional required fees due to our deposit account 03-3875.

Respectfully submitted,

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